IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application

Inventors: John Graeme Houston et al.

Serial No.: 10/535600

Conf. No.: 7535

Filing Date: 5/19/2005

Art Unit: 3754

Examiner: James F. Hook

Docket No.: 9931-008US

Title: Helical Formation for a Conduit

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

PRE-APPEAL BRIEF REMARKS

35 U.S.C. 103 Rejection of Claims 16-27

Claims 16-27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Tayside, EP 1,254,645 (hereinafter "Tayside") in view of Kuhlmann, DE 597,472 (hereinafter "Kuhlmann"). The applicants respectfully traverse the rejection.

The applicants are not disputing the Office's assessment of the disclosure of Tayside. Pending claim 16 is distinguished over Tayside because it recites the feature of the inwardly extending portion extending "between 40% and 60% of the distance from the longitudinal axis to the blood flow tubing to an internal side wall". The technical effect of this feature is that an optimal spiral flow is imparted on blood passing through the conduit (see the paragraphs spanning pages 3 and 4 of the published PCT application for the present invention). The improved spiral flow, in turn, improves blood flow and reduces atherosclerosis and similar pathologies. Thus, the advantage provided by the present invention over Tayside is the provision of a helical formation for a conduit that induces improved blood flow through blood flow tubing, thereby further reducing atherosclerosis and

intimal hyperplasia in a patient. It goes without saying that these are all benefits to the health of the patient.

However, if we consider the situation at the priority date of the present application, it is evident that it would not have been obvious to a skilled person that the combination of the features of Kuhlmann with those of Tayside would have resulted in blood flow tubing which would improve the health of an individual. In fact, the natural instincts of a skilled person in this field would have been to avoid enlarging the fins of the blood flow tubing in Tayside for fear of risking the health of patients. There are several reasons for this.

Firstly, the size of the helical formation proposed by Kuhlmann would have led a skilled person to assume that there would be an unacceptably high risk of occlusion of the blood flow tubing. For example, Figure 2 of Kuhlmann shows a cross-sectional view of a conduit with the proposed size of the helix. It is evident that the open lumen of the conduit has been very significantly reduced in its size. A skilled person would have assumed that in order to improve the health of a patient, it would be important that blood flow tubing not be occluded since any blocking of the blood flow tubing would lead to severe blood flow problems and even death. This view would be reinforced by the fact that in Kuhlmann, the purpose of the helix is "to achieve at a relatively low flow resistance, the maximum vortex and heat emission from the flow medium to the walls of the pipe". Thus, in fact, the skilled person is not taught by Kuhlmann the actual advantage of the height of the helical formation when it is applied to the present invention—namely the improvement in blood flow and the reduction in atherosclerosis and intimal hyperplasia. These advantages actually reduce occlusion of the blood flow tubing because turbulence and dead flow regions of blood within the blood flow tubing are reduced or eliminated.

In addition to this, there would have been an assumption by a skilled person, at the priority date that there would be a tendency for tissue to build up within the blood flow tubing due to turbulence around the helix when it is the size of that proposed by Kuhlmann. In this regard, Kuhlmann reports in page 1 paragraph 2 that the purpose of the height of spiral is to result in "maximum vortex". It is often assumed by experts that increases in vortices in a blood conduit will promote the obturation of the conduit. Again, this prejudice against enlarging the helix formations of the Tayside blood flow tubing has proved to be unfounded because, in fact, increasing the blood of the helical formation in accordance with the present invention improves the spiral blood flow and reduces turbulence.

Furthermore, a skilled person would have had a concern over the tendency of blood to clot and would naturally have assumed that an internal ridge or insert such as the helical

formation of the present application would be expected to promote clotting of the blood flow tubing. Such clotting would only be expected to be worsened by enlarging the helical formation if Kuhlmann were combined with Tayside as suggested in the Office action. Again, this concern proved to be unfounded because the increase in the size of the helical formation rather than maximizing vortex as stated in Kuhlmann actually decreases turbulence.

Nevertheless, there is nothing in Kuhlmann or Tayside which is indicative of this. Therefore, when considering the state of the art at the priority date of the present application, it is evident that the present invention was not obvious.

For these reasons, the applicants respectfully submit that the rejection of claim 16 is traversed. Because claims 17 through 27 are dependent upon claim 16, the applicants respectfully submit that the rejection of those claims is also traversed.

Respectfully,
John Graeme Houston et al.

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